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EPA No.: 68D80056
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TASK No.: 3-30F
September 28, 1990

008139

DATA EVALUATION RECORD

CIDEX

Acute Oral Toxicity Study in Rats

STUDY IDENTIFICATION: Reagan, E.L. Acute oral toxicity study of 806-77-1 in Sprague-Dawley rats. (Unpublished study No. 87.3140.001 conducted by Food and Drug Research Laboratories, Waverly, NY, and submitted by Surgikos, Inc., Arlington, TX; dated January 26, 1988.) MRID No. 412552-18.

APPROVED BY:

Robert J. Weir, Ph.D.
Program Manager
Dynamac Corporation

Signature: William L. McLellan for

Date: Sept. 28, 1990

1. CHEMICAL: Ortho-phthalaldehyde (technical grade), cidex.

2. TEST MATERIAL: 806-77-1, lot No. 07298, was 99.8% pure and was dispensed as a 5% w/v aqueous solution. No other information was available.

3. STUDY/ACTION TYPE: Acute oral toxicity study in rats.

4. STUDY IDENTIFICATION: Reagan, E.L. Acute oral toxicity study of 806-77-1 in Sprague-Dawley rats. (Unpublished study No. 87.3140.001 conducted by Food and Drug Research Laboratories, Waverly, NY, and submitted by Surgikos, Inc., Arlington, TX; dated January 26, 1988.) MRID No. 412552-18.

5. REVIEWED BY:

Patricia Turck, M.S.
Principal Reviewer
Dynamac Corporation

Signature: Patricia Turck
Date: September 28, 1990

Margaret E. Brower, Ph.D.
Independent Reviewer
Dynamac Corporation

Signature: margaret Brower
Date: September 28, 1990

6. APPROVED BY:

Nicolas P. Hajjar, Ph.D.
Department Manager
Dynamac Corporation

Signature: William L. McLellan for
Date: Sept 28, 1990

Irving Mauer, Ph.D.
EPA Reviewer
Toxicology Branch I
(H-7509C)

Signature:
Date: 10/02/90

Karl Baetcke, Ph.D.
EPA Branch Chief
Toxicology Branch I
(H-7509C)

Signature:
Date: 10/22/90

7. CONCLUSIONS:

CORE Classification: CORE Guideline. This study meets all the requirements set forth under EPA Guideline 81-1 for an acute oral toxicity study in rats.

LD_{50}: 121 mg/kg (combined, male, and female).

Toxicity Category: II.

8. SUMMARY: In a preliminary range-finding study, groups of two fasted Sprague-Dawley rats/sex (Charles River Breeding Laboratories, Inc., Wilmington, MA), weighing 191-243 g, were administered single oral doses of 100, 500, or 1000 mg/kg. From the results of this preliminary study, dose levels of 25, 50, 100, 250, or 500 mg/kg were chosen for the main study. Groups of five fasted rats/sex, weighing 217-360 g, were administered single oral doses and observed three times on the day of dosing and twice daily, thereafter, for 14 days. Body weights were recorded on days 1, 4, 8, and 15 of the study. At study termination, animals were subjected to a gross necropsy.

Deaths are summarized in Table 1. Clinical signs observed during the study included ataxia, decreased activity, diarrhea, respiratory irregularity, and apparent urinary incontinence. These effects subsided by study day 7 in surviving animals. Anorexia, salivation, lacrimation, and pale appearance were also noted sporadically during the study. Body weights were reduced by 4, 6 to 10, and 8 to 12% in the 25-, 50-, and 100-mg/kg/day groups, respectively; no animals from the two highest groups survived to day 4. Weight gain was observed in all surviving animals at study days 8 and 15. However, at 100 mg/kg, body weight on study day 15 remained 1 to 2% above or below initial body weight. Findings at necropsy of animals that died during the study included fluid in the abdominal and thoracic cavities; red fluid/substance in the intestines; gray or red firm and thickened gastrointestinal tract; red lungs; pale liver; gray, enlarged, hollow, or fluid-filled kidneys and red fluid in the urinary bladder. Animals surviving to terminal sacrifice had enlarged adrenals, small seminal vesicles, distended stomach, and thickened stomach mucosa with raised white areas. The oral LD_{50} value was 121 mg/kg for both male and female rats and males and females combined.

TABLE 1. Mortality Resulting from Single Oral Dose of 806-77-1 to Rats

Dose Level (mg/kg)	Number of deaths	
	Males	Females
25	0	0
50	0	0
100	1	1
250	5	5
500	5	5

Source: CBI p. 10.

9. REVIEWERS' COMMENTS AND QUALITY ASSURANCE MEASURES: The conduct and reporting of this study were adequate. The oral LD_{50} was 121 mg/kg for both males and females, and the study was classified in Toxicity Category II.

   A signed, but not dated, quality assurance statement was provided.

10. CBI APPENDIX: Appendix, Protocol, CBI pp. 26-31.

APPENDIX

Protocol

(CBI pp. 26-31)

Protocol No. 301
10/87

Pesticide Assessment Guidelines
Subdivision F
Hazard Evaluation
Series 81-1

Protocol
for
Acute Oral Toxicity Study in Rats

FDRL Study No.37.3140.001

Sponsor

Surgikos Company
2500 Arbrook Blvd.
Arlington, Texas 76010

October 28, 1987

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Pages 8 through 12 are not included in this copy.

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